



**UNITED STATES DEPARTMENT OF COMMERCE  
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*W.M.*  
Serial Number: 07/268772 Date: 11/09/88

HETTCH

H 6593187217FH

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06/23/89

☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

**Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:**

- |   |  |
|---|--|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                   |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449.                 | 4. <input type="checkbox"/> Notice of Informal Patent Application, Form PTO-152. |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474.     | 6. <input type="checkbox"/> _____  |

**Part II SUMMARY OF ACTION**

1. ☒ Claims 1-18 are pending in the application.  
Of the above, claims \_\_\_\_\_ are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-18 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings under 37 C.F.R. 1.85 which are acceptable for examination purposes.
8. ☐ Formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. Under 37 C.F.R. 1.84 these drawings are ☐ acceptable, ☐ not acceptable (see explanation or Notice re Patent Drawing, PTO-948).
10. ☐ The proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_ has (have) been ☐ approved by the examiner, ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed on \_\_\_\_\_, has been ☐ approved, ☐ disapproved (see explanation).
12. ☒ Acknowledgment is made of the claim for priority under U.S.C. 119. The certified copy has ☒ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D.-11; 453 O.G. 213.
14. ☐ Other

EXAMINER'S ACTION

The following is a quotation of 35 U.S.C. 103 which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 1-18 are rejected under 35 U.S.C. 103 as being unpatentable over Engel et al in view of Barnes, Ashkenaz, Mendl, or Arp.

Azelastine is a phthalazinone derivative similar in structure to formulas I and II of Engel et al. Engel et al (col. 8, line 4) indicates that his compositions perform in a manner comparable to that of Azelastine. The compositions of Engel et al are antiallergic and are useful in fighting asthma, as are azelastine. The criticality of the percentages and ranges disclosed in claims 2-5 and 18 is not readily apparent to the examiner and should be supported by the submission of comparative data.

Engel et al discloses in col. 8, lines 39-42 that his composition may be applied to the skin and mucous

membranes (presumably including the eye and nose as applicant indicates in claims 1 and 12 azelastine) may be used. The medicament may be in solution. Engel et al discloses (col. 8, line 25) that the solution may be either oily or aqueous. Applicant makes similar disclosures in claims 6, 7 and 10. The solvents of claim 8 are not specifically mentioned in Engel et al. Aerosols are disclosed in col. 8, line 23 of Engel et al. Spraying is disclosed in claim 9 of applicant. Powders are disclosed in col. 8, line 23. Applicant makes similar disclosures in claims 11 and 18.

Barnes discloses droppers for dispensing solutions. Applicant discloses the use of an eye dropper as a dispenser in claim 13.

Ashkenaz discloses a pump sprayer which may be used as applicant discloses in claim 14.

Mendl discloses an atomizer which functions in a manner similar to that disclosed in claims 15 and 16.

Arp discloses a tube for dispensing ointment as disclosed in col. 17.

Claims 13-17 involve using novel compounds in known methods of dispensing. They are rendered obvious by In re Durden, 763 F.2d 1406 (Fed. Cir. 1985).

The motivation to combine Engel et al with Barnes, Ashkenaz, Mendl or Arp stems from the fact that Engel et

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al discloses a medicament and Barnes, etc. disclose means of dispensing this medicament. It would therefore have been obvious to one of ordinary skill in the art of treating bronchial problems that azelastine may be dispensed in the conventional manner disclosed in claims 13-17.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Thomas et al, Vogelsang and Ehbrecht are disclosed as further examples of phthalazinones and dispensing means.

Any inquiry concerning this communication should be directed to Prater at telephone number 703-557-6525.

*P&P* Prater:jaw

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THURMAN K. PAGE  
PRIMARY EXAMINEE  
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